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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,544	11/16/2001	Jon Vein	269/202	3052
34055	7590	05/19/2004	EXAMINER NAFF, DAVID M	
PERKINS COIE LLP POST OFFICE BOX 1208 SEATTLE, WA 98111-1208			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/991,544	Applicant(s) VEIN, JON	
	Examiner David M. Naff	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 and 16-29 is/are pending in the application.
- 4a) Of the above claim(s) 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16-19 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment of May 3, 2004 canceled claims 1-13 and 15, amended claims 14 and 17-19, and added new claims 25-29.

During a telephone conversation on 11/19/03 with applicant's representative, Michael J. Wise, a provisional election was made with traverse to prosecute the invention of I, claims 1-19. The provisional election was affirmed in the amendment of 3/3/04. No reasons have been given why the restriction requirement is improper, and the requirement is adhered to a made final.

Claims 20-23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the office action of 11/24/03 and affirmed the requirement in the amendment of 3/3/04.

Claims 14, 16-19 and 24-29 are examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 14, 16-19, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowlin et al (6,592,623 B1) in view of Vacanti et al (6,348,069 B1).

The claims are drawn to a method of providing nutrition to a subject by providing the subject with a non-human meat product produced by culturing non-human muscle cells ex vivo, seeding the

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cells onto a support structure and growing the cells to produce a non-human meat product suitable for consumption.

Bowlin et al disclose producing engineered muscle for use as an implant to replace dysfunctional muscle tissue by culturing cells that
5 form muscle tissue in the presence of a matrix to produce muscle tissue (col 3, lines 5-10 and col 10, lines 1-28). The cells used may be stem cells or muscle cells (col 7, line 21 and col 11, line 27).

Vacanti et al discloses producing engineered tissues by expanding bovine, ovine or lamb muscle cells in culture, seeding the cells on a
10 scaffold and growing the cells to confluence (col 8, lines 32-61).

When desiring to replace dysfunctional muscle tissue in an animal such as a bovine, ovine or lamb, it would have been obvious to produce the engineered muscle of Bowlin et al for such replacement, and it would have been obvious use as the cells to form the muscle, cells
15 from a bovine, ovine or lamb as suggested by Vacanti et al using muscle cells from these animals to engineered tissue by culturing muscle cells, seeding the cells on a scaffold and growing the cells to confluence.

The resultant engineered muscle tissue for the animal will be
20 non-human and produced by culturing muscle cells ex vivo, and will inherently be meat that can be consumed. The fact that the muscle tissue produced by Bowlin et al is intended as an implant does not make it non-consumable. The procedure of Bowlin et al will result in engineered muscle substantially free of microbial contamination as
25 required by claim 19. Bowlin et al disclose using electrical pacing

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(col 12, lines 40-41) that would suggest using an electrical current as in claims 16. Skeletal muscle implant is disclosed by Bowlin et al (col 10, line 30), and using skeletal muscle cells as in claim 24 would have been obvious. Stem cells are also disclosed by Bowlin et al as noted above. Pluri-potent and toti-potent stem cells as in claim 25 are well known cells, and their use would have been obvious. Moreover, it appears stem cells of Bowlin et al are inherently such cells. Incorporating nutrients as in claim 17 would have been obvious to supply nutrients for cell growth.

Response to Arguments

Applicant urges that the claims now require a method of using a non-human meat product to provide nutrition to a subject. However, the claims do not require a step of the subject consuming the meat product as food to obtain nutrition. Engineered muscle tissue produced as set forth above will inherently be capable of providing nutrition to a subject.

Claim Rejections - 35 USC § 103

Claims 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 14, 16-19, 24 and 25 above, and further in view of Skaar et al (5,746,649) and Naughton et al (5,863,531).

Claims 26 and 27 require seeding non-human fat cells on the support structure and growing the fat cells in conjunction with the non-human muscle cells, and claims 28 and 29 require seeding non-human

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cartilage cells on the support structure and growing the cartilage cells in conjunction with the non-human muscle cells.

Skaar et al disclose (col 1, lines 17-37) that meat contains fat cells and connective tissue dispersed throughout muscle tissue.

5 Naughton et al disclose growing stromal cells with cells of another type on a support (col 4, lines 25-30), and after forming stromal tissue on the support, inoculating the support with tissue specific cells (paragraph bridging cols 13 and 14).

When using animal cells to form the engineered muscle tissue of
10 Bowlin et al as set forth above, it would have been obvious to include adipocyte cells (fat cells) and cartilage cells with the muscle forming cells since fat cells and cartilage are normal components of muscle tissue as disclosed by Skaar et al, and including these cells would have been expected to make the muscle tissue of Bowlin et al
15 more similar to natural muscle tissue. It would have been apparent from Naughton et al that different cell types can be cultured together.

Response to Arguments

Applicant points out that these claims depend on claim 14.

20 However, for the reason set forth above, the argument traversing the rejection of claim 14 is unpersuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE**

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FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN

15 5/17/04